



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/630,355	07/30/2003	Carsten Momma	117163.00077	9258

21324 7590 11/16/2006
HAHN LOESER & PARKS, LLP
One GOJO Plaza
Suite 300
AKRON, OH 44311-1076

EXAMINER

PELLEGRINO, BRIAN E

ART UNIT	PAPER NUMBER
----------	--------------

3738

DATE MAILED: 11/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/630,355

Applicant(s)

MOMMA ET AL.

Examiner

Brian E Pellegrino

Art Unit

3738

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 September 2006.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-29 is/are pending in the application.
4a) Of the above claim(s) 16-25 is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1, 3-15 and 26-29 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1,3-13,26-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wu et al. (6254632). Wu et al. disclose (Fig. 2B) a stent having a base body with a plurality (col. 8, lines 50-56) of microdevices **200** that project from the implant surface to form a microcannula **218** on the outer surface to engage the vessel wall, col. 6, lines 13-17. Please note the intended use of the “microcannulae” to “penetrate into the media of the blood vessel” carries no weight in the absence of any distinguishing structure. Wu also discloses the thickness of the cover is from 25-500 μ m, col. 9, lines 13,14. Wu additionally discloses that the protrusions or “microcannulae” can extend out of the cover, col. 9, lines 17-19. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have a height of a protrusion or “micorcannulae dimension that falls within the claimed range of 100 to about 400 μ m since it would need to have a dimension as such in order to protrude through the cover having the thickness range between if it were 300 to 500 μ m as disclosed by Wu, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233. Fig. 4A shows a cover layer **420** of biodegradable material (col. 6, lines 33-42) that closes the active substance **410** in the deposit. The microdevices are fully capable of being applied using hybrid technology. Wu additionally discloses the active substance

is liberated once the stent is implanted and the microcannulae engage the vessel wall, col. 6, lines 18-26. Wu discloses the stent can be made from a biodegradable material and from a magnesium alloy, col. 4, lines 43,44,47,48,54.

With respect to claims 3,4 Wu does disclose the lengths or depths of the microcannulae can be any dimension depending on the amount of drug desired to be delivered, col. 6, lines 61-66. However, Wu fails to disclose the lengths of the microcannulae to be 180 μ m-250 μ m. It would have been an obvious matter of design choice to modify the length of the microcannulae, since applicant has not disclosed that using a length of 150 μ m or 180 μ m provides any advantage, or solves a stated problem, or is used for any particular purpose. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the length taught by Wu et al. or the claimed lengths in claim(s) 3,4 because both stents perform the same function of delivering a therapeutic substance to a vessel and anchoring the stent in the wall.

Claims 14,15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wu et al. '632 in view of Hossainy et al. (6287628). Wu et al. is explained supra. However, Wu fails to disclose the use of a biodegradable drug carrier to hold the active substance. Hossainy et al. teach that impregnated polymers can be used to hold therapeutic materials to place in the microcannulae (col. 9, lines 21-25) and that biodegradable carriers can be used, col. 10, lines 50-52,57-59. It would have been obvious to one of ordinary skill in the art to use a biodegradable carrier to hold the drug

and fill the microcannulae as taught by Hossainy in the stent of Wu et al. such that it degrades over time and has a controlled release rate at the implantation site.

Response to Arguments

Applicant's arguments filed 9/8/06 have been fully considered but they are not persuasive. In response to applicant's argument that Wu's protrusions on the stent cannot penetrate the media of a blood vessel, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. Wu clearly discloses "microcannulae" as claimed and Applicant has failed to distinguish any structural feature. Applicant states the protrusion of Wu's stent has dimensions that would not penetrate the media. However, this is an improper statement because the Applicant arbitrarily selected a dimension less than what Applicant's claims recite. MPEP 2144.05 states a prior art reference that discloses a range encompassing a somewhat narrower claimed range is sufficient to establish a prima facie case of obviousness." *In re Peterson*, 315 F.3d 1325, 1330, 65 USPQ2d 1379, 1382-83 (Fed. Cir. 2003).

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within


Art Unit: 3738

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian E Pellegrino whose telephone number is 571-272-4756. The examiner can normally be reached on M-Th (6:30am-4pm) and alternate Fridays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached at 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

TC 3700, AU 3738


BRIAN E. PELLEGRINO
PRIMARY EXAMINER